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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,448	11/07/2001	Sidney N. Wolfe	PP16166.003	5486

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EXAMINER

ANDRES, JANET L

ART UNIT PAPER NUMBER

1646

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/010,448

**Applicant(s)**

WOLFE ET AL.

**Examiner**

Janet L. Andres

**Art Unit**

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 29 December 2003 is acknowledged. Claims 1-78 are pending and under examination in this office action.

#### ***Claim Rejections Withdrawn***

2. The rejection of claims 1-9, 26-29, and 32-40 under 35 U.S.C. 102(b) or 103(a) as anticipated by or unpatentable over WO 95/31479 or WO 95/31213 is withdrawn in response to Applicant's arguments that neither document teaches highly purified mannitol as instantly claimed. While each document contemplates pharmaceutical compositions, mannitol is available in a USP-grade injectible form and it is assumed that Applicant's preparation is more pure than what is commercially available.

3. The rejection of claims 1-9, 26-29, and 32-40 under 35 U.S.C. 112, second paragraph, as indefinite in the recitation of "variants" is withdrawn in response to Applicant's amendment deleting the word.

#### ***Claim Rejections Maintained/New Grounds of Rejection/Objection***

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on p. 10, lines 17. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

5. Claims 1-78 are newly rejected as indefinite in the recitation of "biologically active". "Biologically active" is not defined in the specification; what is presented on p.11 of the specification is a list of desired, not required properties. Thus the artisan would not know what was encompassed by the phrase.

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6. Claims 1-78 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods and compositions using mannitol from USP purified by the steps set forth on p. 6, lines 1-2, of the specification, does not reasonably provide enablement for all forms of highly purified mannitol meeting the limitations of the definition on p. 5, lines 24-26. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman*, (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

According to Applicant's arguments in the response filed 29 December 2003, the purity of the mannitol is crucial. It appears that Example 2 and 3 what has been tested is mannitol that has been methanol extracted, carbon treated, and ultrafiltered. Applicant's definition of "highly purified" encompasses, however, all forms with "a low level" of reducing activity. There is no guidance in the specification to indicate that forms other than those purified as set forth in examples 2 and 3 would exhibit the desired enhanced stability. There is no guidance to indicate what particularly is required for the desired effects and there are no working examples for any other forms of purification or any other starting materials. It is not predictable that other forms of purification, or other starting materials, would result in end products having the equivalent

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purity; "the reducing activity" and other means to remove it are not described. Thus, without further guidance, it would require undue experimentation for one of skill in the art to practice the invention as broadly claimed.

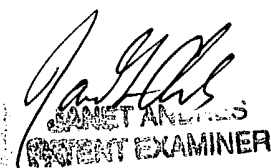
NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday-Thursday and every other Friday, 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.  
18 March 2004



JANET ANDRES  
PATENT EXAMINER